Hemostasis Innovation is Here.

HEMOSIL® ACUSTAR
ADAMTS13 ACTIVITY ASSAY

Introducing the first automated, on-demand assay for TTP diagnosis and monitoring



werfen

Excellent analytical performance on the ACL AcuStar system

Time-to-first result	33 min	
On-board stability	56 days	
Linearity	0.2–150%	
Interferences	Hemoglobin	None up to 500 mg/dL
	Bilirubin	None up to 18 mg/dL
	Triglycerides	None up to 1,250 mg/dL
	Rheumatoid Factor (RF)	Presence of RF can cause underestimation
	Human Anti-Mouse Antibody (HAMA)	None up to 1 µg/mL
	von Willebrand Factor (VWF)	None up to 200 IU/dL (200%)
	Heparin (LMWH, UFH)	None up to 2 IU/mL

Method comparison

Method comparison studies were performed on the ACL AcuStar system against both ELISA and FRET assays with clinically characterized TTP and other TMA samples. HemosIL AcuStar ADAMTS13 Activity assay demonstrated excellent correlation between methods.

N	Slope	Intercept	r	Comparative Method
105	0.975	2.617	0.943	**ELISA**
100	0.970	7.617	0.970	**FRET**

On-demand testing for fast, informed clinical decisions

HemosIL AcuStar ADAMTS13 Activity assay* is **the first automated, on-demand test** to aid in the diagnosis and monitoring of Thrombotic Thrombocytopenic Purpura (TTP), with the superior analytical sensitivity of chemiluminescence technology.

HemosIL AcuStar ADAMTS13 Activity assay*: Fully automated solution for fast, informed clinical decisions

A rapid, on-demand solution with superior analytical sensitivity and unmatched simplicity for the ACL AcuStar Hemostasis testing system—improving care, quality and efficiency.

Simple, fast and always ready

- No labor-intensive or manual testing processes required
- Rapid, with first results in approximately 30 minutes
- 8-week onboard stability allows 24/7 on-demand testing

Superior analytical sensitivity with reliable chemiluminescence technology

- Extended linearity quantifies ADAMTS13 activity to 0.2%
- Traceable to World Health Organization ADAMTS13 activity 1st International Standard, ensuring result accuracy



*Not FDA 510(k)-cleared and Health Canada licensed.
Not saleable in US and Canada.

TTP and ADAMTS13 activity

TTP: Potentially deadly and difficult to diagnose[1]

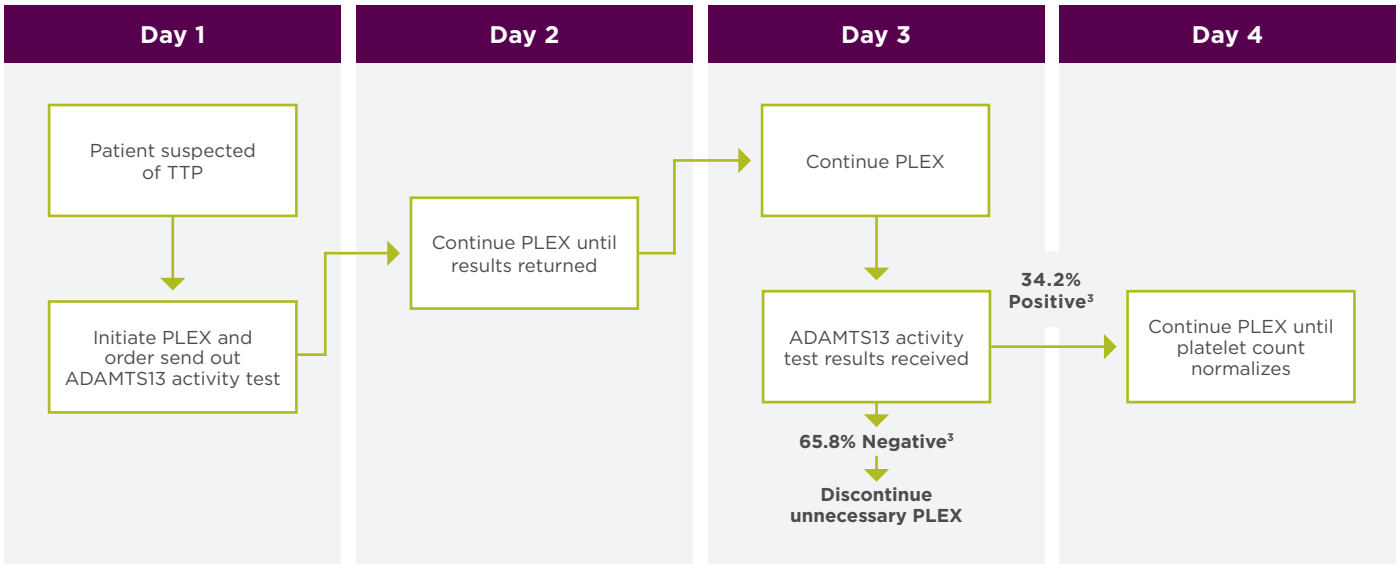
- Life-threatening disease where platelet-rich thrombi form in microvasculature due to ADAMTS13 activity deficiency (VWF protease)
- This rare hematologic disease which requires differential diagnosis to distinguish from other thrombotic microangiopathies (TMA)
- 90% mortality rate if untreated, 10%–20% if promptly treated
- Plasma exchange (PLEX) is standard-of-care treatment—initiated immediately (recommended within 4–8 hours of presentation) in patients suspected of TTP[2]

ADAMTS13 activity

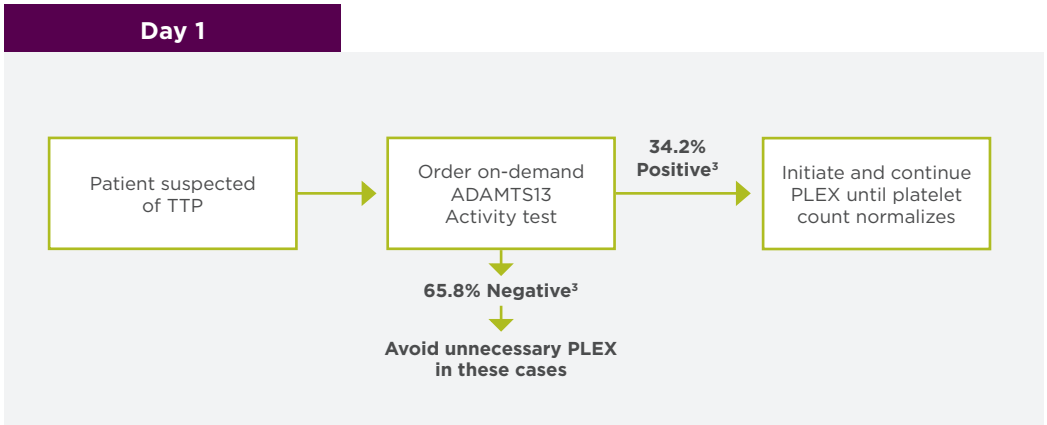
- The only biologic marker specific for TTP
- Current laboratory testing methods (e.g., ELISA, FRET) require specialty lab with turnaround times up to 3 days[3,4]

HemosIL AcuStar ADAMTS13 Activity assay helps improve quality of patient care and efficiency when TTP is suspected

Scenario 1: Send out ADAMTS13 activity test while initiating PLEX



Scenario 2: On-demand ADAMTS13 Activity assay

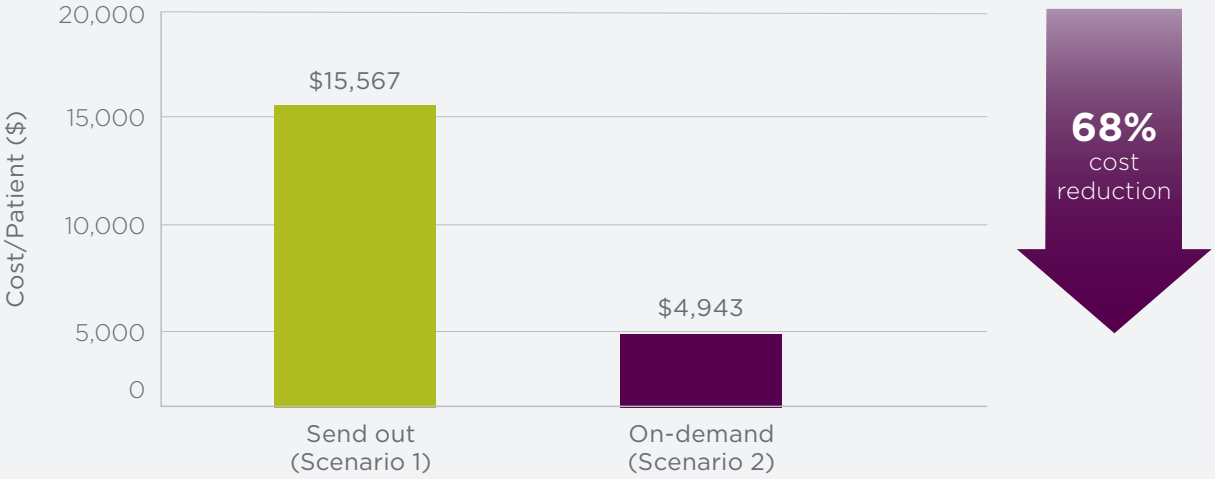


On-demand ADAMTS13 activity testing expedites time to results for cost control and improved patient care

Limitations of send out testing while initiating PLEX

- Send out ADAMTS13 activity testing can require several days for results[4]
- PLEX should only be used when necessary, due to associated increased mortality, morbidity and related costs[3,7]
- PLEX has limited efficacy in treating other TMAs[5,6,8]

Total economic impact of send out vs on-demand ADAMTS13 activity testing[3]



Improve patient care

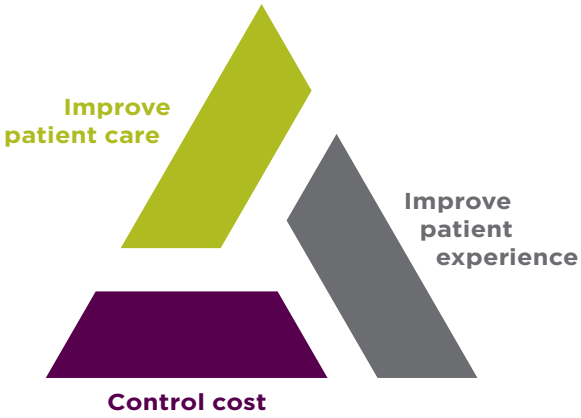
- Faster patient management decisions
- Demonstrated to reduce unnecessary PLEX procedures

Improve patient experience

- Demonstrated to reduce morbidity

Control costs

- Eliminates unnecessary PLEX procedures
- Decreases PLEX utilization



HemosIL®

NEW HemosIL AcuStar ADAMTS13 Activity kit composition

Product	Part Number	Kit Configuration
HemosIL AcuStar ADAMTS13 Activity Assay*	0009802048	Cartridge (25 tests) Calibrator 0, 1 x 1mL (liq) Calibrator 1, 1 x 1mL (lyo) Calibrator 2, 1 x 1mL (lyo) Resuspension Buffer 1 x 1.8mL (liq)
HemosIL AcuStar VWF Controls*	0009802119	Low VWF Control 3 x 1mL Normal VWF Control 3 x 1mL

*Not FDA 510(k)-cleared and Health Canada licensed. Not saleable in US and Canada.

Meet time-critical demands of TTP management

References

1. Joly BS, Coppo P, Veyradier A. Thrombotic thrombocytopenic purpura. *Blood.* 2017;25;129(21):2836–2846.
2. Scully M, Hunt BJ, Benjamin S, Liesner R, Rose P, Peyvandi F, et al. Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies. *Br J Haematol.* 2012;158:323–335.
3. Kim CH, Simmons SC, Williams LA, Staley EM, Zheng XL, Pham HP. ADAMTS13 test and/or PLASMIC clinical score in management of acquired thrombotic thrombocytopenic purpura: a cost-effective analysis. *Transfusion.* 2017;57:2609–2618.
4. Martin IW, Katus MC, Martin CB, Szczepiorkowski ZM, Gorham JD, Dunbar NM. Rapid ADAMTS13 availability impacts treatment for microangiopathic hemolytic anemia and thrombocytopenia. *J Clin Apher.* 2016;31(5):419–422.
5. Bendapudi PK, Li A, Hamdan A, Fry AM, Uhl L, Marques M, et al. Derivation and prospective validation of a predictive score for the rapid diagnosis of thrombotic thrombocytopenic purpura: the plasmic score. *Blood.* 2014;124:231.
6. Bendapudi PK, Li A, Hamdan A, Uhl L, Kaufman R, Stowell C, et al. Impact of severe ADAMTS13 deficiency on clinical presentation and outcomes in patients with thrombotic microangiopathies: the experience of the Harvard TMA Research Collaborative. *Br J Haematol.* 2015;171:836–844.
7. Page EE, Kremer Hovinga JA, Terrell DR, Vesely SK, George JN. Thrombotic thrombocytopenic purpura: diagnostic criteria, clinical features, and long-term outcomes from 1995 through 2015. *Blood Adv.* 2017;1(10):590–600.
8. Li A, Makar RS, Hurwitz S, Uhl L, Kaufman RM, Stowell CP, et al. Treatment with or without plasma exchange for patients with acquired thrombotic microangiopathy not associated with severe ADAMTS13 deficiency: a propensity score-matched study. *Transfusion.* 2016;56:2069–2077.

Corporate Headquarters

Plaza de Europa, 21–23
08908 L'Hospitalet de Llobregat
Barcelona, Spain
+34-93-4010101

Headquarters and Technology Center, Hemostasis and Acute Care Diagnostics

180 Hartwell Road
Bedford, MA 01730-2443
USA
+1-781-861-0710

Worldwide Locations

The Americas

Brazil
São Paulo
+55-11-46227878

Canada
Richmond Hill, ON
+1-800-552-2025 x6115

Colombia
Bogotá
+57-15-221-052

Mexico
Mexico City
+52-55-5262-1760

Uruguay
Montevideo
+5982-481-81-33

USA
Bedford, MA
+1-781-861-0710

Asia-Pacific

Australia
Sydney
+61-02-9098-0200

China
Beijing
+86-10-59756055

Hong Kong
+852-2792-7773

Shanghai
+86-21-66308671

India
New Delhi
+91-490-29-550

Japan
Tokyo
+81-3-5419-1301

Korea
Seoul
+82-1899-9217

Thailand
Bangkok
+66-271-226-28/9

Europe

Austria
Vienna
+43-1-256-58-000

Belgium
Brussels
+32-2-7252052

Czech Republic
Prague
+420-246-090-931

France
Paris
+33-182-30-86-00

Germany
Munich
+49-89-909070

Hungary
Budapest
+36-1-882-73-10

Italy
Milan
+39-02-25221

Lithuania
Kaunas
+370-37-313157

The Netherlands
Breda
+31-76-5480100

Poland
Warsaw
+48-22-336-18-00

Portugal
Lisbon
+351-214247312

Russia
Moscow
+7-499-124-45-59

Spain
Barcelona
+34-902-20-30-90

UK
Warrington, England
+44-1925-810141

werfen.com

For more information, contact your local Werfen sales representative or distributor.

ACL, ACL AcuStar, ACL Elite, ACL TOP, HemoCell, HemoHub, HemosIL, ReadiPlasTin, RecombiPlasTin, SynthAFax and SynthASil are trademarks of Instrumentation Laboratory Company and/or one of its subsidiaries or parent companies and may be registered in the United States Patent and Trademark Office and in other jurisdictions. The Werfen logo is a trademark of Werfen and may be registered in the Patent and Trademark Offices of jurisdictions throughout the world. All other product names, company names, marks, logos and symbols are trademarks of their respective owners.

©2021 Instrumentation Laboratory. All rights reserved.

ATS13Bro EUROW Rev00 09/21

werfen